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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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May 10, 2019

Mr. Mike Mason
Senior Vice President
Lilly Connected Care and Insulins Global Business Unit
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Mason:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, April 10, 2019, at the hearing entitled "Priced out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, May 24, 2019. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by e-mail in the Word document provided with this letter to Jourdan Lewis, Policy Analyst with the Committee, at jourdan.lewis@mail.house.gov. You do not need to send a paper copy of your responses to the Committee. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Ms. Lewis at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachments

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

   a. Where can patients find information on eligibility and criteria for the programs?

   b. What are the eligibility criteria for the programs?

   c. What information and documents must patients submit in order to qualify for the programs?

   d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

   e. What are the ten most common reasons your company denies a patient's application?

   f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

   g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

   a. Where can patients find information on eligibility and criteria for the programs?

b. What are the eligibility criteria for the programs?

c. What information and documents must patients submit in order to qualify for the programs?

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

e. What are the ten most common reasons your company denies a patient's application?

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

The Honorable Brett Guthrie (R-KY)

1. In March 2019, Eli Lilly announced that it was launching an authorized generic version of Humalog. In a staff briefing, Eli Lilly said that it anticipated providing supplemental rebates for the authorized generic version of Humalog.

   a. Will Eli Lilly request that Pharmacy Benefit Managers (PBMs) include both the authorized generic and the brand version on their formularies? If so, why? Does Eli Lilly anticipate that one version of the product will be preferred on the formularies over the other version of the product?

   b. Will the introduction of the authorized generic have any impact on the list or net pricing for the branded version of Humalog (*e.g.*, will the rebates Eli Lilly offers to PBMs for Humalog change)?

2. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Eli Lilly received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Eli Lilly lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Eli Lilly and describe the requirements set forth in the letter.

    a. Does Eli Lilly have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.

    b. Has Eli Lilly provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.

    c. What happens to Eli Lilly's rebate obligations with PBMs if Eli Lilly lowers the list price of insulin or any other medicine?

    d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Eli Lilly's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.

3. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Eli Lilly's testimony, Eli Lilly described how the net price of its most broadly used insulin product decreased by 8.1 percent while the list price increased by 51.9 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.

4. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are sometimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.

    a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

    b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

   Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

   So, which is it? Is there innovation in the insulin market or not?

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?